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DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

LEO A. FARMER, M.D.
DECISION AND ORDER

On July 12, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Leo A. Farmer, M.D. (Applicant), of Baton Rouge, Louisiana. The Show Cause Order proposed the denial of Applicant's application for a DEA Certificate of Registration as a practitioner on the ground that his "registration would be inconsistent with the public interest." GX 2, at 1 (citing 21 U.S.C. § 823(f)).

The Show Cause Order specifically alleged that Applicant had previously held a practitioner's registration, which had expired on March 31, 2010, and that "[f]rom April 1 to November 5, 2010, [he had] authorized 3,497 controlled substances prescriptions" for various schedule III and IV controlled substances including phentermine, diethylpropion, and phendimetrazine. *Id.* at 1-2. The Show Cause Order further alleged that because his registration had expired, Applicant violated 21 U.S.C. §§ 841(a)(1) and 843(a)(2), as well as 21 CFR 1306.03. *Id.* at 1.

Next, the Show Cause Order alleged that on August 18, 2010, Applicant had issued prescriptions for Adipex-P 37.5mg, a schedule IV controlled substance, to two confidential sources. *Id.* at 2. The Show Cause Order alleged that Applicant had acted outside of the usual course of professional practice and lacked a legitimate medical purpose because each of the two confidential sources did not have a Body Mass Index (BMI) which met "the medically

recognized criteria for [being] ‘overweight’ or ‘obese.’” Id. (citing 21 U.S.C. § 841(a)(1) and 21 CFR 1306.04). With respect to the first confidential source, the Order further alleged that his/her BMI was 17.4 and that the source had said that “he/she was not interested in weight loss, merely weight maintenance.” Id.

The Show Cause Order also notified Applicant of his right to either request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for electing either option, and the consequences of failing to do either. Id. at 2-3. On July 15, 2011, the Government accomplished service by Certified Mail addressed to him at the address he listed on his application. GX 3. Since the date of service of the Order, thirty days have now passed and neither Applicant, nor any one purporting to represent him, has filed a request for a hearing or submitted a written statement in lieu of a hearing. I therefore find that Applicant has waived his right to a hearing or to submit a written statement in lieu of a hearing and issue this Decision and Final Order based on relevant evidence contained in the record submitted by the Government. 21 CFR 1301.43(d) & (e). I make the following findings.

FINDINGS

Applicant is a physician who practices at a clinic in Baton Rouge, Louisiana. GX 7, at 1. Applicant previously held a DEA Certificate of Registration as a practitioner; however, on March 31, 2010, Applicant allowed his registration to expire. GX 4. Applicant did not file an application for a new DEA registration until October 5, 2010. Id.

According to the affidavit of a DEA Task Force Officer (TFO), Applicant came to the attention of the Agency during the investigation of a person who was suspected of obtaining controlled substances through fraud. GX 7, at 1. According to the TFO, between August 2009 and April 2010, this person went to Applicant’s clinic eight times and “[o]n seven of those

occasions . . . was prescribed weight-loss medications despite clear indications that she was not in need of the medications.” Id. However, when on the eighth occasion, clinic personnel, who had determined that this person was also obtaining prescriptions for weight loss drugs from another physician, confronted her with this information, she fled “and never returned.” Id.

Subsequently, on August 18, 2011, two confidential sources (hereinafter, CS1 and CS2) conducted undercover visits at Applicant’s clinic during which they wore recording devices. Id. at 2. According to the TFO’s affidavit, Applicant asked CS1: “[w]hy are you so skinny?” Id. CS1 told Applicant that “he/she did not wish to lose weight, but just to maintain his/her current weight.” Id. After noting that his clinic was primarily for weight loss, Applicant stated, “but I guess we can handle maintenance.” Id. Applicant issued CS1 a prescription for Adipex-P 35mg tablets. Id.

In his affidavit the TFO further stated that “CS1 is 5’7” tall, weighs 111 pounds and has a BMI of 17.4.” Id. The TFO also asserted that “CS1 does not meet the generally recognized criteria as overweight or obese and is, in fact, underweight according to her BMI.” Id.

As for CS2’s visit, according to the TFO’s affidavit, Applicant told him/her that his/her weight was normal and asked “why he/she believed he/she [wa]s overweight?” Id. CS2 told applicant that “he/she wanted to lose weight around his/her stomach.” Id. Again according to the TFO, Applicant told CS2 “that losing five pounds would not do much good and weight loss would not be targeted at a specific area of the body.” Id. Applicant issued CS2 a prescription for Adipex-P 35mg. Id. at 3.

According to the TFO, “CS2 is 4’11” tall, weighs 104 pounds and has a BMI of 21.” Id. at 2. The TFO further asserted that “CS2 does not meet the generally recognized criteria as overweight or obese.” Id. at 2-3.¹

During the course of the investigation, a DEA Diversion Investigator (DI) also determined that Applicant had allowed his registration to expire on March 31, 2010. Affidavit of DI, at 1. According to the DI, the Louisiana Board of Pharmacy has granted DEA access to its Prescription Monitoring Program (PMP) database through a dedicated computer located in a different office. Id. at 2. The DI then requested that a DI with access to the PMP obtain a printout of the prescriptions issued by Applicant between March 1 and November 20, 2010; a copy of the printout was submitted as part of the record as GX 5. Id.

According to the DI, the PMP data show “that from April 1, 2010 until November 5, 2010, [Applicant] issued 3,497 prescriptions for controlled substances.” Id. However, as found above, Applicant had allowed his registration to expire on March 31, 2010. The PMP data show that Applicant prescribed such drugs as diethylpropion, phentermine, Adipex-P (also phentermine), each of which is a schedule IV stimulant, as well as phendimetrazine, a schedule III stimulant. See GX 5; see also 21 CFR 1308.13(b), 1308.14(e).

DISCUSSION

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner's registration may be denied upon a determination "that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. § 823(f). In making the

¹ In his affidavit, the TFO further stated that “[a]ccording to guidelines published by the American Medical Association, the U.S. Department of Health and Human Services, the Centers for Disease Control, the National Institute for Health [sic], the National Heart, Lung and Blood Institute and the North American Association for the Study of Obesity, pharmacotherapy should be used on patients with a Body Mass Index (BMI) over 30 or with a BMI over 27 when certain risk factors for disease or concomitant obesity exist.” GX 7, at 2.

public interest determination in the case of a practitioner, Congress directed that the following factors be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing . . . controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Id.

"[T]hese factors are considered in the disjunctive." Robert A. Leslie, 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether . . . to deny an application. Id. Moreover, I am "not required to make findings as to all of the factors." Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005) (citing Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005)).

In this matter, while I have considered all of the factors,² I conclude that the Government's evidence with respect to Applicant's experience in dispensing controlled substances (factor two) and his compliance with applicable laws related to controlled substances

² The Government produced no evidence (other than Applicant's application for a DEA registration) regarding his state licensure status; this document suggests that he possessed a Louisiana medical license at the time he submitted his application. GX 1, at 1. It also produced no evidence as to whether he has been convicted of an offense related to the distribution or dispensing of controlled substances. However, even assuming that Applicant currently holds a valid state license which authorizes him to dispense controlled substances, this factor is not dispositive of the public interest determination "because the DEA has [a] separate oversight responsibility with respect to controlled substances." MacKay v. DEA, 2011 WL 6739420, *9 (10th Cir. Dec. 23, 2011). So too, even assuming that Applicant has not been convicted of a felony related to the distribution or dispensing of controlled substances, this is not dispositive because there are multiple reasons why a person may not have been convicted (or even prosecuted) for such an offense. Id.

(factor four) establishes that issuing a registration to Applicant “would be inconsistent with the public interest.” 21 U.S.C. § 823(f). Accordingly, the application will be denied.

Factors Two and Four – The Applicant’s Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

As noted above, in the Show Cause Order, the Government alleges two separate bases for concluding that Applicant’s registration would be inconsistent with the public interest. First, it alleges that Respondent violated the CSA by prescribing controlled substances without a DEA registration. Second, it alleges that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed Adipex-P (phentermine) to the two CSs. I address the latter contention first.

Under a longstanding DEA regulation, a prescription for a controlled substance is not “effective” unless it is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a). This regulation further provides that “an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. § 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.” *Id.*; see also 21 U.S.C. § 802(10) (defining the term “dispense” as meaning “to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance”) (emphasis added); see also La. Rev. Stat. Ann. § 40:961(33) (2008);³ La. Rev. Stat. Ann. § 40:1238.2(A) (2008).⁴

³ Louisiana law defines the term “prescription” to mean “a written request for a drug . . . issued by a licensed physician . . . for a legitimate medical purpose, for the purpose of correcting a physical, mental, or bodily ailment, and acting in good faith in the usual course of his professional practice.” La. Rev. Stat. Ann. § 40:961(33).

⁴ This statute provides that:

As the Supreme Court has explained, “the [CSA’s] prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” Gonzales v. Oregon, 546 U.S. 243, 274 (2006) (citing United States v. Moore, 423 U.S. 122, 135, 143 (1975)).

Under the CSA, it is fundamental that a practitioner must establish and maintain a bonafide doctor-patient relationship in order to act “in the usual course of . . . professional practice” and to issue a prescription for a “legitimate medical purpose.” Laurence T. McKinney, 73 FR 43260, 43265 n.22 (2008). The CSA generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. See Kamir Garces-Mejias, 72 FR 54931, 54935 (2007); United Prescription Services, Inc., 72 FR 50397, 50407 (2007); but see 21 U.S.C. § 829(e)(2)(B) (providing federal standard for prescribing over the internet). See also United States v. Smith, 573 F.3d 639, 647-48 (8th Cir. 2009) (noting that even after Gonzales v. Oregon, 546 U.S. 243 (2006), courts of appeals “have applied a general-practice standard when determining whether the practitioner acted in the ‘usual course of professional practice’”); United States v. Merrill, 513 F.3d 1293, 1306 (11th Cir. 2008) (“The appropriate focus is not on the subjective intent of the doctor, but rather it rests upon whether the physician prescribed medicine ‘in accordance with a standard of medical practice generally recognized and accepted in the United States.’”) (quoting Moore, 423 U.S. at 139 (1975)).

A prescription, in order to be effective in legalizing the possession of legend drugs, shall be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs. An order purporting to be a prescription issued to a drug abuser or habitual user of legend drugs, not in the course of professional treatment, is not a prescription within the meaning and intent of this Section. Any person who knows or should know that he or she is filling such a prescription or order to a drug abuser or habitual user of legend drugs, as well as the person issuing the prescription, may be charged with a violation of this Section.

La. Rev. Stat. Ann. § 40:1238.2(A).

In support of its contention that Applicant acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed phentermine to the two CSs, the Government notes that neither CS's BMI met "medically recognized criteria for [being] 'overweight' or 'obese.'" Request for Agency Action at 6. With respect to CS1, it further contends that the CS stated that "he/she was not interested in weight loss, merely weight maintenance." Id.

The Government's contention that the prescriptions violated 21 CFR 1306.04(a) and were unlawful distributions under the CSA thus appears to rest on the theory that this drug can only be lawfully prescribed to a person who meets the criteria for being overweight or obese. Notably, the Government does not cite to any standards adopted by the Louisiana Board of Medical Examiners which govern the prescribing of medications in the treatment of weight loss.⁵ Nor does the Government contend that the evaluation conducted by Applicant on the two CSs was medically inadequate to support the prescribing of Adipex-P. Finally, the Government provided no evidence establishing what indications Adipex-P is approved for, nor evidence that it is medically inappropriate to prescribe this drug to a person who does not meet the criteria for being overweight or obese but who seeks to maintain a particular weight.⁶

In Gonzales, the Supreme Court explained that the CSA and its case law "amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as

⁵ While in his affidavit, the TFO asserted that under various guidelines, "pharmacotherapy should be used on patients with a [BMI] over 30 or with a BMI over 27 when certain risk factors for disease or concomitant obesity exist," this does not establish the truth of the converse, i.e., that it is medically unjustified to use pharmacotherapy for patients who have lower BMIs or who wish to maintain a certain weight. Moreover, in his affidavit, the TFO did not set forth any evidence that he possesses medical expertise and is thus competent to opine on the medical appropriateness of the prescriptions Applicant issued to the CSs.

⁶ Furthermore, the Government produced no evidence that either CS made clear to Applicant that they were seeking the drugs for the purpose of abusing them or selling them to others.

conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally.” 546 U.S. at 270. Thus, even if Adipex-P has not been approved by the Food and Drug Administration for marketing for the indication of weight maintenance, this alone would not establish a violation of the CSA’s prescription requirement because a physician can lawfully prescribe a drug, including a controlled substance, for an off-label use as long as the physician acts in the usual course of professional practice and has a legitimate medical purpose for doing so. Rather, as set forth in a legion of Agency cases, what establishes a violation of this provision (in a proceeding under section 303 or 304) is proof by substantial evidence that a prescription was issued outside of the usual course of professional practice and lacked a legitimate medical purpose. 21 CFR 1306.04(a). As to this, the Government’s evidence is lacking. Accordingly, the allegations related to the prescriptions Applicant issued to the CSs are not supported by substantial evidence.

The allegation that Applicant issued numerous prescriptions after he allowed his registration to expire is, however, supported by substantial evidence. Under Federal law, “[e]very person who dispenses . . . any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him,” 21 U.S.C. § 822(a)(2), and “[e]xcept as authorized by” the CSA, it is “unlawful for any person knowingly or intentionally . . . to distribute[] or dispense . . . a controlled substance.” *Id.* § 841(a)(1); see also 21 CFR 1301.11(a), *id.* 1306.03(a)(2). Moreover, it “unlawful for any person knowingly or intentionally . . . to use in the course of the . . . dispensing of a controlled substance . . . a registration number which is . . . expired[.]” 21 U.S.C. § 843(a)(2). See also 1301.13(a) (“No person required to be registered shall engage in any activity for which registration is

required until the application for registration is granted and a Certificate of Registration is issued”).

As found above, the Government produced a printout from the Louisiana Board of Pharmacy’s Prescription Monitoring Program showing that from April 1, 2010, the day after Applicant’s registration expired, through November 5, 2010, he issued nearly 3,500 prescriptions for schedule III and IV controlled substances including phendimetrazine, diethylpropion, and phentermine. The issuance of each prescription is a separate violation of the CSA and DEA regulations. See 21 U.S.C. §§ 822(a)(2), 841(a)(1), 843(a)(2); 21 CFR 1301.11(a); id. 1306.03(a)(2). Accordingly, I hold that the evidence pertaining to Applicant’s experience in dispensing controlled substances (factor two) and compliance with applicable laws related to controlled substances (factor four) establishes that the issuance of a registration to him “would be inconsistent with the public interest.” 21 U.S.C. § 823(f). Accordingly, I will deny the application.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f) and 28 CFR 0.100(b), I order that the application of Leo A. Farmer, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective [Insert Date Thirty Days from the Date of Publication in the Federal Register].

Dated: May 4, 2013

Michele M. Leonhart
Administrator

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